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Diabetes Research
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White coat adherence effect on glucose control in adult individuals with diabetes

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ARTICLE INFO

Article history:

Received 28 March 2020

Received in revised form

6 August 2020

Accepted 21 August 2020

Available online 25 August 2020

Keywords:

White coat adherence

Diabetes

Glycemic control

continuous glucose monitoring (rt/isc CGM)

ABSTRACT

Background: White coat adherence (WCA) is defined as an increased adherence to treatment regimens directly before a visit with a healthcare provider. Little is known on the effect of WCA on glucose control in adult patients with diabetes mellitus.

Methods: The present study is based on 618 CGM-observations of 276 patients with diabetes treated between January 2013 and July 2018. The analysis compares data from the 3 days prior to a visit (p1) with the preceding 25 days (p2).

Results: Sensor use was higher during p1 than p2 ($92.8 \pm 7.3\%$ vs $88.8 \pm 7.5\%$; $p < 0.001$). Mean glucose [MG] and coefficient of variation [CV] were lower in p1 compared to p2 (MG 163.9 ± 39.2 mg/dL vs 166.9 ± 35.7 mg/dL, $p = 0.001$; CV $33.5 \pm 8.4\%$ vs $36.0 \pm 7.0\%$, $p < 0.001$; respectively). Time in range (70–180 mg/dL) was higher in p1 than p2 ($61.4 \pm 21.2\%$ vs $60.0 \pm 18.4\%$, $p = 0.002$). Sensitivity-analysis showed that WCA effect was mainly detected in patients with $HbA_{1c} > 7\%$ [53 mmol/mol].

Conclusion: This study reveals a WCA effect on pre-visit glucose control in adult patients with diabetes. The effect was most pronounced in patients with moderate to poor glycemic control. In these patients, analysis of CGM data should encompass a minimum of 1 to 2 weeks prior to a consultation.

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1. Introduction

Impaired adherence to medication and treatment regimens is a relevant issue and may affect up to 50% of patients with chronic conditions such as diabetes [1]. From drug studies it is known that compliance with prescription is significantly

higher immediately before and after clinical visits compared to the time period in between the visits [2–5]. The increased adherence to treatment regimens in the days prior to the visit with a healthcare provider (HCP) is generally referred to as white coat adherence (WCA) and may lead to misinterpretation of general glycemic control if the time period is not cho-

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<https://doi.org/10.1016/j.diabres.2020.108392>

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sen adequately. This may have implications for clinical decision-making and can even result in erroneous or missing treatment adaptations [6].

WCA has been reported in children and adolescents with diabetes, increasing the frequency of blood glucose measurements, insulin boluses and carbohydrate documentation before a HCP visit [7,8]. However, there is currently no study formally assessing a potential WCA effect on glycemic control in adult patients with diabetes. The increasing availability of continuous and intermittent scanning glucose monitoring (rtCGM & iscCGM) devices provides an optimal framework for a detailed analysis of a potential WCA effect on glycemia.

The present study aimed at assessing a potential WCA effect on glucose control in adult patients with diabetes based on rt/iscCGM readings prior to a clinical visit. The hypothesis was that glucose control is significantly better in the days directly before a visit as compared to the previous period.

2. Methods

This was an observational, retrospective single-center study approved by the local ethics committee. A general informed consent for the analysis of health-related data was obtained for all participants. We screened all patients with diabetes treated at our tertiary diabetic referral center between January 2013 and July 2018 who were using a rt/iscCGM system. A study of pediatric patients with epilepsy demonstrated an increase in adherence during the 3 days preceding a clinical visit [6]. Based thereon, we assessed WCA by comparing sensor-related glucose data of day 0 to day -3 prior to the visit (p1) with the period between day -4 to day -28 before the visit (p2). As a secondary analysis to assess for an extended WCA effect, we compared a longer pre-visit period (day 0 to day -7, p1_{ext}) with the period between day -8 and day -28 (p2_{ext}). Since current consensus guidelines recommend a sampling period of at least 2 weeks we further compared the 14 days prior to the visit (p1_{equal}) with the preceding 14 days (p2_{equal}) [9]. To corroborate the validity of shorter-term CGM-data we analysed the correlation between the full 28 days and sampling periods of 3, 7, 14 and 21 days prior to the clinical visit. Furthermore, we compared correlation of p1/p2, p1_{ext}/p2_{ext} and p1_{equal}/p2_{equal} with the full 28 days.

According to current guidelines, patients were only included in the analysis if rt/iscCGM-data were available for at least 70% of the two corresponding time periods [9]. Additional inclusion criteria were a diagnosis of diabetes mellitus according to ADA guidelines [10], age > 16 years, and written informed consent for the retrospective analysis of CGM data.

CGM records were exported from the proprietary manufacturers' software and then processed using the Glyculator 2.0 web application, which is a validated tool for analyzing CGM records [11]. Patient characteristics including diabetes duration, treatment modality and HbA_{1c} values were obtained from electronic medical records. Diabetes duration was calculated based on the time-point of diagnosis denoted in the medical record. All statistical analyzes were performed using STATA version 16.0 (StataCorp LLC, College Station, Texas, USA). Unless otherwise specified, results are reported as mean ± standard deviation (SD). Time periods were compared

using paired t-tests and mixed linear models with patient as a random effect. Analysis of potentially modifying factors was performed using ANOVA and multivariable mixed model analysis including age, sex, type and duration of diabetes, and type of treatment.

Correlation of the individual CGM parameters over the different sampling periods was assessed using correlation coefficients with listwise deletion of missing values. An alpha level of 5% was defined as statistically significant.

3. Results

Out of 433 screened patients, 276 fulfilled the inclusion criteria for the main analysis (64.1% male, 35.9% female; mean HbA_{1c} 7.4 ± 1.1% [57 ± 12 mmol/mol], mean age 47.0 ± 16.7yr s, mean diabetes duration 17.3 ± 12.2yrs; additional patient characteristics are summarized in Table 1). This resulted in a total of 618 observations, both 3 and 25 days prior to the visit. For the secondary analysis of extended periods p1_{ext} and p2_{ext}, 274 patients met the inclusion criteria, resulting in 616 observations. For periods p1_{equal} and p2_{equal}, 263 patients fulfilled the inclusion criteria, resulting in 587 observations.

The results of the analysis comparing p1 to p2, and p1_{ext} compared to p2_{ext} are given in Table 2. Sensor use was higher during p1 compared to p2 (92.5 ± 7.3% vs 88.8 ± 7.5%; p < 0.001)

Table 1 – Patient characteristics.

Characteristics	Overall population (n = 276)
Observations	618
Observations per patient	2.24 ± 1.56
Age [years]	47.0 ± 16.7
Gender [n (%)]	
Female	99 (35.9%)
Male	177 (64.1%)
HbA _{1c} [% (mmol/mol)]	7.4 ± 1.1 (57 ± 12)
Diabetes duration [years]	18.2 ± 12.3
Type of diabetes [n (%)]	
Type 1	189 (68.5%)
Type 2	62 (22.5%)
Pancreatogenic	14 (5.1%)
GDM	1 (0.3%)
MODY	2 (0.7%)
unknown	8 (2.9%)
Treatment modality [n (%)]	
MDI	129 (46.8%)
CSII	98 (35.5%)
Non-insulin	2 (0.7%)
Insulin + non-insulin	44 (15.9%)
unknown	3 (1.1%)
CGM device [n (%)]	
Medtronic enlite	60 (21.7%)
Dexcom	64 (23.2%)
Free Style libre	152 (55.1%)

Patient characteristics of individuals included in the main analysis (p1 vs p2). GDM, gestational diabetes; MODY, maturity-onset diabetes of the young; MDI, multiple daily injections; CSII, continuous subcutaneous insulin infusion; non-insulin encompasses oral antidiabetic drugs and/or GLP-1 receptor agonists.

Table 2 – rt/isc CGM parameters prior to clinical visits.

	p1 (day 0 to –3)	p2 (day –4 to –28)	p-value	p1 _{ext} (day 0 to –7)	p2 _{ext} (day –8 to –28)	p-value
Sensor in use (%)	92.5 ± 7.3	88.8 ± 7.5	<0.001	91.1 ± 6.9	88.9 ± 7.6	<0.001
HbA _{1c} ≤ 7%	92.8 ± 6.8	89.4 ± 7.2	<0.001	91.7 ± 6.3	89.7 ± 7.3	<0.001
HbA _{1c} > 7%	92.3 ± 7.5	88.5 ± 7.7	<0.001	90.7 ± 7.3	88.5 ± 7.7	<0.001
Mean glucose (mg/dl)	163.9 ± 39.2	166.9 ± 35.7	0.001	165.3 ± 37.4	166.9 ± 35.4	0.042
HbA _{1c} ≤ 7%	142.4 ± 26.0	142.7 ± 20.8	0.67	142.8 ± 24.0	142.7 ± 21.2	0.87
HbA _{1c} > 7%	178.5 ± 40.2	183.0 ± 34.9	0.002	180.2 ± 37.7	182.6 ± 34.3	0.044
Time in range (70–180 mg/dl)	61.4 ± 21.2	60.0 ± 18.4	0.005	61.1 ± 19.7	60.0 ± 18.5	0.011
HbA _{1c} ≤ 7%	73.4 ± 15.8	73.0 ± 11.8	0.48	73.1 ± 13.6	73.0 ± 12.3	0.85
HbA _{1c} > 7%	53.5 ± 20.8	51.4 ± 17.1	0.010	53.2 ± 19.4	51.7 ± 17.1	0.018
Time > 180 mg/dl	34.3 ± 22.2	35.9 ± 19.7	0.002	34.8 ± 20.9	36.0 ± 19.6	0.012
HbA _{1c} ≤ 7%	21.3 ± 15.8	21.7 ± 12.2	0.58	21.6 ± 14.0	21.6 ± 12.5	0.98
HbA _{1c} > 7%	42.8 ± 21.8	45.3 ± 18.1	0.003	43.5 ± 20.3	45.2 ± 17.9	0.015
Time > 250 mg/dl	11.3 ± 14.9	12.5 ± 13.7	<0.001	11.9 ± 14.3	12.4 ± 13.6	0.068
HbA _{1c} ≤ 7%	4.7 ± 7.7	4.6 ± 5.4	0.83	4.8 ± 6.8	4.7 ± 5.7	0.75
HbA _{1c} > 7%	15.9 ± 16.9	17.7 ± 15.1	0.002	16.6 ± 16.1	17.4 ± 15.0	0.11
Time < 70 mg/dl	4.3 ± 6.8	4.1 ± 4.7	0.40	4.1 ± 5.3	4.0 ± 4.6	0.77
HbA _{1c} ≤ 7%	5.2 ± 6.7	5.3 ± 5.5	0.74	5.3 ± 5.8	5.4 ± 5.6	0.71
HbA _{1c} > 7%	3.7 ± 6.8	3.3 ± 4.0	0.16	3.3 ± 4.8	3.1 ± 3.6	0.50
Time < 54 mg/dl	1.4 ± 4.1	1.3 ± 2.3	0.42	1.3 ± 3.0	1.3 ± 2.2	0.92
HbA _{1c} ≤ 7%	1.6 ± 4.1	1.6 ± 2.6	0.99	1.6 ± 3.0	1.7 ± 2.8	0.49
HbA _{1c} > 7%	1.3 ± 4.1	1.1 ± 2.0	0.28	1.1 ± 2.9	1.0 ± 1.8	0.67
CV (%)	33.5 ± 8.4	36.0 ± 7.0	<0.001	34.7 ± 7.6	35.8 ± 7.1	<0.001
HbA _{1c} ≤ 7%	33.1 ± 8.0	35.2 ± 6.6	<0.001	34.4 ± 7.1	35.2 ± 7.0	0.021
HbA _{1c} > 7%	33.9 ± 8.7	36.4 ± 7.4	<0.001	35.0 ± 8.1	36.2 ± 7.3	<0.001
MAGE (mg/dl)	135.4 ± 40.5	143.8 ± 33.2	<0.001	146.3 ± 43.7	150.9 ± 40.9	<0.001
HbA _{1c} ≤ 7%	121.7 ± 34.7	127.4 ± 26.1	0.012	127.3 ± 36.7	128.1 ± 32.0	0.65
HbA _{1c} > 7%	149.9 ± 41.4	159.7 ± 32.1	<0.001	159.3 ± 44.1	164.7 ± 39.8	0.001
MODD (mg/dl)	58.2 ± 21.7	59.4 ± 15.4	0.18	63.5 ± 22.4	63.6 ± 19.0	0.87
HbA _{1c} ≤ 7%	50.7 ± 16.3	52.0 ± 12.4	0.27	54.2 ± 17.5	53.6 ± 15.3	0.47
HbA _{1c} > 7%	66.6 ± 24.1	66.7 ± 14.5	0.91	70.2 ± 23.4	70.1 ± 18.5	0.93

HbA_{1c} 7% = 53 mmol/mol. For comparison p1 vs. p2 n = 618 (HbA_{1c} ≤ 7% n = 235, HbA_{1c} > 7% n = 350, HbA_{1c} not available n = 33); For comparison p1_{ext} vs. p2_{ext} n = 616 (HbA_{1c} ≤ 7% n = 231, HbA_{1c} > 7% n = 350, HbA_{1c} not available n = 35). Significant p-values are printed in bold.

and also during p1_{ext} compared to p2_{ext} (91.1 ± 6.9% vs 88.9 ± 7.6%; $p < 0.001$). For p1 compared to p2 mean glucose (163.9 ± 39.2 mg/dL vs. 166.9 ± 35.7 mg/dL; $p = 0.001$), CV (33.5 ± 8.4% vs. 36.0 ± 7.0%; $p < 0.001$) and mean amplitude of glycemic excursion [MAGE] (135.4 ± 40.5 mg/dL vs. 143.8 ± 33.2 mg/dL; $p < 0.001$) were significantly lower. Time in target range (TIR 70–180 mg/dL) was higher in p1 than p2 (61.4 ± 21.2% vs 60.0 ± 18.4%, $p = 0.005$), whereas time above 180 mg/dL was lower in p1 compared to p2 (34.3 ± 22.2% vs 35.9 ± 19.7%, $p = 0.002$) and this was also observed for time above 250 mg/dL (11.3 ± 14.9% vs 12.5 ± 13.7%; $p < 0.001$). There was no difference for time below 70 mg/dL (4.3 ± 6.8% vs. 4.1 ± 4.7%, $p = 0.4$).

For the comparison of p1_{ext} and p2_{ext} differences tended to be smaller but were still present for sensor use, mean glucose, TIR, time > 180 mg/dL and parameters of glucose variability (Table 2). When comparing p1_{equal} and p2_{equal} only marginal differences were detectable for TIR, time > 180 mg/dL and MAGE (see supplementary data).

When stratifying analysis according to HbA_{1c}, differences were more pronounced in patients with moderate to poor control (HbA_{1c} > 7% [53 mmol/mol]) for all the glycemic parameters except time in low glucose range and mean of daily differences. In well-controlled patients (HbA_{1c} ≤ 7% [53 mmol/mol]) only sensor use, CV and MAGE were lower

in p1 compared to p2 (Table 2). However, there were no significant differences ($p > 0.05$ for all comparisons) according to diabetes treatment (CSII, MDI, other), type of diabetes (DM1, DM2, other), gender, age (grouping by decade), or diabetes duration (<10y, 10–20y, >20y).

To account for the multiple observations in several individuals, we performed a sensitivity analysis using a mixed linear model with patient as a random effect. The results remained similar, corroborating the robustness of our findings ($p < 0.001$ for sensor use, $p = 0.002$ for mean glucose, $p = 0.008$ for TIR, $p = 0.004$ for time > 180 mg/dL, $p = 0.001$ for time > 250 mg/dL, $p = 0.40$ for time < 70 mg/dL, $p = 0.42$ for time < 54 mg/dL and $p < 0.001$ for CV, respectively). However, WCA effect differed according to glycemic control (HbA_{1c} ≤ 7% vs. > 7%, Table 2), particularly for mean glucose ($p = 0.034$) and for time > 250 mg/dL ($p = 0.017$). This finding was robust even if models were adjusted for age, sex, type and duration of diabetes, and treatment type ($p = 0.034$ and 0.019, respectively).

To assess overall validity of our dataset and as suggested by previous investigators [12] we assessed the correlation of each parameter during the individual sampling periods (i.e. 3, 7, 14, and 21 consecutive days prior to the visit) with the full 28 days (see Fig. 1). Overall, there was an increasing correlation for all CGM parameters when extending the sampling

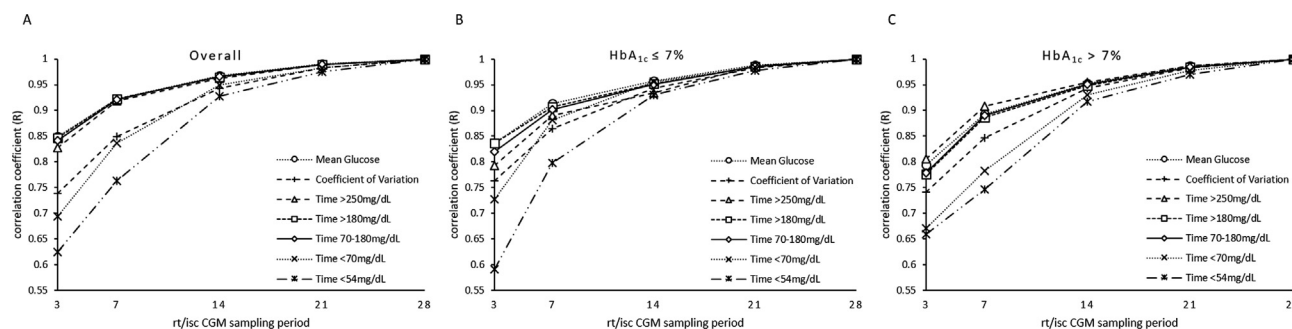


Fig. 1 – Correlation coefficient (R) between the full 28 days and increasing number of sampling days prior to a clinical visit for differing real-time and intermittent scanning continuous glucose monitoring (rt/isc CGM) metrics in the overall population (panel A), in individuals with $HbA_{1c} \leq 7\%$ [53 mmol/mol] (panel B) and individuals with $HbA_{1c} > 7\%$ [53 mmol/mol] (panel C).

period (see Fig. 1A). Well controlled individuals ($HbA_{1c} \leq 7\%$ [53 mmol/mol]) showed a higher correlation between days 3, 7, 14, 21 and the full 28 days for all CGM-parameters, except for time < 54 mg/dl (see Fig. 1B) compared to moderately/poorly controlled patients (see Fig. 1C). This discrepancy was especially pronounced for shorter time-periods before a visit (i.e. 3 and 7 days) and decreased with longer time-periods.

4. Discussion

The main findings of the present analysis assessing white coat adherence (WCA) based on rtCGM and iscCGM data in adult patients with diabetes are fourfold: First, we found a significantly improved glucose control in the days directly prior to a clinical visit; Second, the effect was consistent across all parameters under investigation; Third, the effect was more pronounced in patients with moderate to poor glycemic control (i.e. HbA_{1c} values $\geq 7\%$ [53 mmol/mol]); And fourth, the effect diminished over the first week prior to a visit and was absent when the period was extended to 2 weeks.

To the best of our knowledge, the present study thereby is the first to assess a WCA effect on glucose control in adult patients with diabetes. The fact that differences between a three-day period compared with the previous 25 days were consistently observed and revealed statistical significance points towards an adequately powered sample size and corroborates the concept of a true WCA effect on glucose control in adult individuals with diabetes. In the present study, the effect was mainly reflected by a higher time in target range and a higher percentage of sensor use, as well as lower mean glucose, time above target, and coefficient of variation.

Our findings of a WCA effect are in line with two recent reports in children and adolescents with diabetes showing more frequent blood glucose measurements, carbohydrate inputs, and delivered insulin boluses prior to a clinical visit [7,8]. However, both studies did not include CGM data and therefore, no conclusion could be drawn regarding diabetes control in the days prior to the visits in this pediatric populations. Of interest, in the present analysis besides parameters of glycemic variability no relevant WCA effect was observed in well-controlled patients (i.e. $HbA_{1c} \leq 7\%$ [53 mmol/mol]), although these patients also showed a significantly higher sensor utilization prior to the visit. This lat-

ter finding may be related to the fact that patients with better control generally have a higher adherence, thereby minimizing the need and the potential to further optimize therapy before visits.

In our analysis, WCA effect was most strongly observed when the analysis was focused on the 3 days prior to a visit. This is fully in line with pharmacological studies in other areas of medicine (e.g. HIV, neurology, etc) typically demonstrating a WCA effect across the 2–3 days preceding contact with healthcare providers [3,6]. When extending the period of assessment, the effect in the present analysis diminished over the first week and was absent when comparing the first 2 weeks to the 2 weeks before. In a clinical setting this indicates that when analyzing CGM data, particularly in patients with moderate to poor overall control, the influence of a potential WCA effect can be minimized by extending the analysis period to 2 weeks prior to a visit. Of note, 2 weeks is a generally accepted time period for the interpretation of CGM results since previous studies have shown good correlation with longer term glycemic control. For instance, a recent study by Riddlesworth et al. demonstrated that correlation between long-term glycemic control and CGM-metrics improved with increasing number of days of data collection, plateauing at sampling duration of around 14 days [12]. This is well in line with our findings, showing a robust and similar increase of correlation coefficients over time. Of interest, the lower correlation of CGM parameters between the first 3 days and the full 28 days prior to a visit in moderately/poorly controlled patients further corroborates the hypothesis of a more pronounced WCA effect in this population. Noteworthy, for time below target range we found generally a more modest correlation between shorter pre-visit periods (i.e. 3 and 7 days) and the full 28 days. Based on this longer time periods should be considered to allow for a robust assessment of hypoglycemia risk when analyzing CGM read-outs both in moderately/poorly controlled patients, but also in well-controlled individuals.

While the present study is based on a careful analysis of data, we have to acknowledge several limitations. First, this was a retrospective study. Therefore, we cannot entirely rule out selection bias and systematic errors. We tried to minimize this by including every patient treated with a rt/iscCGM at our department. Still, this was a single center study at a tertiary referral center with Caucasian predominance, thereby limit-

ing generalization to other populations. On the other hand, the sample size was substantial and covered a wide range of patients with diabetes, and effects were consistently observed across all subgroups. Third, we had no access to CGM-data of the time-period after the clinical visits, precluding statements regarding a sustained WCA effect after visits. This aspects needs to be covered in future prospective studies. Fourth, while absolute difference in some parameters was relatively small, particularly in well-controlled patients, the effect was more pronounced in patients with moderate to poor glycemic control, thereby pointing towards higher clinical importance in this latter group. Fifth, time point of diabetes diagnosis was based on information derived from the medical record. Therefore, we cannot exclude that some of the patients previously suffered from undiagnosed diabetes leading to an underestimation of diabetes duration, particularly for type 2 diabetes. However, since the present analysis is focused on changes in diabetes control directly prior to a consultation, this is unlikely to have interfered with the interpretation of the results.

5. Conclusion

The present study is the first to report on a WCA effect on glucose control by showing a significantly improved glucose control based on rt/iscCGM in the days directly prior to a clinical visit in adult patients with diabetes. The effect was consistent, and was most pronounced in patients with moderate to poor glycemic control. Based on these findings, analysis of CGM data, particularly in adult patients with non-optimal diabetes control, should encompass a period of adequate length (i.e. a minimum of 1–2 weeks) before consultation to avoid misinterpretation due to WCA.

Declaration of Competing Interest

The authors declared that there is no conflict of interest.

Acknowledgments

We thank all patients who provided their data for this analysis.

Appendix A. Supplementary material

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.diabres.2020.108392>.

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